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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Masanori NAKASU et al.  
Appl. No. : 10/534,360  
(National Stage of PCT/JP2003/014174)  
I.A. Filed : November 7, 2003  
For : OSTEOGENIC TREATMENT DEVICE  
Group Art Unit : Not Yet Assigned  
Examiner : Not Yet Assigned

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Service Window, Mail Stop AMENDMENT  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir :

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§1.97-1.98, Applicants hereby bring the following information to the attention of the Examiner in charge of the above-identified application, which includes information cited and discussed in the specification and the International Search Report issued in connection with International Patent Application No. PCT/JP03/014174, of which the present application is the U.S. National Stage Application. A copy of the International Search Report was enclosed with the papers when entering the National Stage on May 9, 2005. The Examiner is invited to review these materials to inspect the relevance indicated during international examination with respect to the documents cited therein. The following is a list of the documents cited in the above-noted documents:

International Patent Publication No. WO 95/22611, together with patent family members U.S. Patent No. 5,763,416, U.S. Patent No. 5,942,496, U.S. Patent No. 5,962,427, U.S. Patent No. 6,074,840, and U.S. Patent Application Publication No. 2002/0193338;

International Patent Publication No. WO 93/04710, together with patent family members U.S. Patent No. 5,270,300;

U.S. Patent No. 6,340,648, together with patent family member Japanese Laid-open Patent Publication No. 2000-302567, together with an English language abstract and an English language machine-translation of the same;

U.S. Patent Application Publication No. 2002/0022885, together with patent family member Japanese Laid-open Patent Publication No. 2002-017846, together with an English language abstract and an English language machine-translation of the same;

International Patent Publication No. WO 98/21972, together with patent family members Japanese Laid-open Patent Publication No. 2001-505097, together with an English language abstract and an English language machine-translation of the same. Applicants note that the Japanese document is cited on page 2 of the specification of the present application; and

International Patent Publication No. WO 97/38729.

Applicants also wish to bring the following information to the attention of the Examiner in charge of the above-identified application:

Journal of Biomedical Materials Research, Ichiro Ono, Tohru Tateshita, et al., "Prostaglandin E<sub>1</sub> and recombinant bone morphogenetic protein effect on strength of hydroxyapatite implants," Vol. 45, Iss. 4 , Pp. 337–344 (1999).

Baltzer AW, Lattermann C, et al., "Genetic enhancement of fracture repair: healing of an experimental segmental defect by adenoviral transfer of the BMP-2 gene." Gene Ther. 2000 May; 7(9):734-9.

Further to 37 C.F.R. §1.98 (a)(2)(ii), copies of the U.S. patents and the U.S. patent application publications are not enclosed herewith. However, if any copies are needed, the Examiner is respectfully requested to contact the undersigned.

Applicants respectfully request that the Examiner consider the above material and cite the same. Copies of the above-noted foreign documents are enclosed together with a duly completed Form PTO-1449. The Examiner is accordingly requested to consider each of these documents, and to make them of record in this application by initialing in the appropriate spaces on the Form PTO-1449. Applicants respectfully request that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office.

Applicants note that an Office Action on the merits has not issued in the present application, and thus no fee is believed necessary to ensure consideration of the submitted material.

Should there be any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,  
Masanori NAKASU et al.

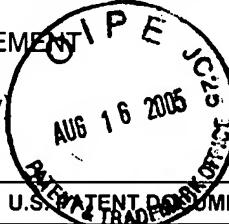


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FORM PTO-1449

U.S. Department of Commerce  
Patent and Trademark OfficeAtty. Docket No.  
P27827Application No.  
10/534,360INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT  
(Use several sheets if necessary)Applicant  
Masanori NAKASU et al.Filing Date  
November 7, 2003Group  
Not Yet Assigned

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5 7 6 3 4 1 6	06/09/98	BONADIO et al.			
		5 9 4 2 4 9 6	08/24/99	BONADIO et al.			
		5 9 6 2 4 2 7	10/05/99	GOLDSTEIN et al.			
		6 0 7 4 8 4 0	06/13/00	BONADIO et al.			
2002	0 1 9 3 3 3 8		12/19/02	GOLDSTEIN et al.			
	5 2 7 0 3 0 0		12/14/93	HUNZIKER			
	6 3 4 0 6 4 8		01/22/02	IMURA et al.			
2002	0 0 2 2 8 8 5		02/21/02	OCHI			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
95	/ 2 2 6 1 1		08/24/95	W.I.P.O			
93	/ 0 4 7 1 0		03/18/93	W.I.P.O			
2000	- 3 0 2 5 6 7		10/31/00	JAPAN			X
2002	- 0 1 7 8 4 6		01/22/02	JAPAN			X
98	/ 2 1 9 7 2		05/28/98	W.I.P.O			
2001	- 5 0 5 0 9 7		04/17/01	JAPAN			X
97	/ 3 8 7 2 9		10/23/97	W.I.P.O			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	English Language Abstract of JP 2000-302567.
2	English Language Abstract of JP 2002-017846.
3	English Language Abstract of JP 2001-505097.
4	Journal of Biomedical Materials Research, Ichiro Ono, Tohru Tateshita, et al., "Prostaglandin E <sub>1</sub> and recombinant bone morphogenetic protein effect on strength of hydroxyapatite implants," Vol. 45, Iss. 4 , Pp. 337-344 (1999)
5	Baltzer AW, Lattermann C, et al., "Genetic enhancement of fracture repair: healing of an experimental segmental defect by adenoviraltransfer of the BMP-2 gene." Gene Ther. 2000 May; 7(9):734-9.

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.